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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,407	11/14/2003	Steven M. Menchen	4119C7	2023

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,407

Applicant(s)

MENCHEN ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/01/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☒ Claim(s) no is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

The following restriction was discussed with applicants' representative Mr. Powers on 20 April 2005:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 are, drawn to a method of detecting electrophoretically separated classes of DNA classified in class 435 subclass 6.
- II. Claims 7-10, and 11-21 are drawn to a compound, classified in class 532 subclass 24.3 and DNA detection kit containing labeled oligonucleotides classified in class 536 subclass 24.3.

The inventions are distinct from each other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case 4,7 dichlorofluorescein dye can be used to as a label on a protein or the fluorescein dye oligonucleotides (depending on the oligonucleotide used can be used in a process of detecting DNA

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binding proteins which is a materially difference process than detecting DNA, and is for example classified in Class 435, subclass 7.1.

Because the inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Upon due consideration, no restriction is made and the claims are rejected as set forth below.

DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 contains the trademark/trade name SequenaseTM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a nucleic acid polymerase and, accordingly, the identification/description is indefinite because the product enzyme can be changed absent a change in the product name.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-21 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-36 of U. S. Patent No. 6,649,598B2. The conflicting claims are not patentably distinct from each other because the claims of the patent are to polynucleotides comprising 4, 7-dichlorofluorescein dyes. The subject matter claimed in the instant application is fully disclosed in the claims of the patent and is covered by the claims of the patent. Thus, the patent and the application claim the same common subject matter as obvious variations.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 7, 12 of U.S. Patent No. 4,855,225. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a method of

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detecting up to four classes of oligonucleotides separated by gel electrophoresis, and in the instant application a method of detecting a plurality of electrophoretically separated, classes of DNA. The differences between the claims of the patent and that of the claims of the application are to plurality of electrophoretically separated classes of DNA, whereas the claims of the patent are for the detection of up to four classes of oligonucleotides, separated by gel electrophoresis.

Thus claims 1-21 are directed to an inventions not patentably distinct from the claims of the two above indicated U.S. Patents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Fung et.al. US Patent 4,855,225 ('225) issued Aug. 8, 1989 who are another to the current inventive entity, filed February 7, 1986.

The instant application claim 1 claims a method of detection, oligonucleotides conjugated to a fluorescent dye, to detect oligonucleotides. Fung et al. anticipate the

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instant claim by teaching: disclosure of a method, use of a dye to detect of classes of oligonucleotides as shown in the abstract and entire publication.

The instant application claim 2 shows a dye defined by a formula. Fung et al. teach of a formula (column 2 line53-64). The formula is identical with the core structure of the formula claimed in the instant application and the different substituents are identified in claims 3-6.

The Instant application claims 3-6 shows the formula with the different substituents, A', B', X' and Z(1-6): A' is a hydrogen or a group that maybe converted to a linking functionality, B' is a fluoro or an acidic group, X' a hydrogen, Z (1 -6) a hydrogen or converted to a linking functionality.

Fung et al. anticipate the instant claims by teaching or illustrating the different linking functionalities of the above to the extent that X' is hydrogen or A' suitable for use with the structure/formula illustrated in columns 2 and 3 of the patent ('225,) it is anticipated that these substituents would have been attached to the core compound made by Fung et al. as these substituents can be taken alone to fit the description indicated in the instant application in claims 3-6.

Claims 7-10 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Fung et.al. US Patent 4,855,225 ('225) issued Aug. 8,1989 who are another to the current inventive entity, filed February 7, 1986.

The instant application claims a compound having a formula, with multiple substituted substituents A', B', X' and Z(1-6) with linking functionalities. Fung et al.

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anticipate the instant claims by teaching a compound with the same core structure identified in the claim.

With respect to the different substituents on the structure, Fung et al. describe A' as a linking functionality, B' as an acidic anionic group, X' as hydrogen, and Z(3-4) as hydrogen, halo compounds or a group that maybe converted to a linking functionality column 4 line 35-59.

Fung et al. also teach a compound where A' is a carboxyl, B' is a carboxyl, X' is hydrogen and Z(3-4) are hydrogen or halo compounds. From the structures in the application and the description, A', X', Z(1-6) are hydrogen base on standard chemical nomenclature, and can further be of a linking functionality as taught by Fung et al. which is claimed.

Fung et al teach that B' is the same substituent in the claim (see column 4 line 54-59 of the reference).

Claim Rejections - 35 USC § 103

Claims 11-21 are rejected under 35 U.S.C. 103(a) as obvious over Fung et.al. US Patent 4,855,225 ('225) issued Aug. 8,1989 who are another to the current inventive entity, filed February 7, 1986. in view of Ausubel et al., eds., (1988) Current Protocols in Molecular biology pp 3-23 and 3-24 and U. S.Biochemicals Cooperation (1988) Enzymes and Reagents For Molecular Biology.

Applicants claim (11-15 and 18) a kit to detect electrophoretically separated oligonucleotides conjugated to a fluorescent dye (4, 7-dichlorofluorescein dye), that

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consist of an enzyme, i.e., a nucleic acid polymerase, a reaction buffer and a nucleoside triphosphate mix.

Fung et al. disclose polynucleotide conjugated to a fluorescein dye of claim 11 but does not per se set forth a "kit". The reference teaches the parts of the currently claimed kit and therefore makes the invention of claim 11- obvious to one of ordinary skill in the art. Fung et al. also teach a reaction buffer at column 10 line 11-12. The reference disclosed a nucleic acid polymerase (i.e., a DNA polymerase which requires a template that is enzymatically extended in the presence of a radioactively labeled deoxyribonucleoside triphosphate at column 11 line 42-45. Although Fung et al did not per se teach of the use of a nucleic acid ligase (DNA polymerases have a known ligase function), it would have been readily apparent to one skilled in the art that for a DNA chain growth reaction, there needs to be a nucleic acid ligase or a polymerase. It would have been apparent to one skilled in the art to incorporate an annealing enzyme as set forth by Ausubel et al. (Current Protocols in Molecular biology pp 3—23-3-24) to effect chain elongation especially where Fung et al. at column 10 teach that the polymerase is for effecting DNA synthesis. Thus, claims 11, 12 and 14 are considered obvious and within the skill in the art to have made and used at the time the invention was made.

Claims 13 and 15 refer to reaction mixes containing nucleoside triphosphates. As to these claims, Fung et al. teach in column 10+ that the multiple dextyribonucleotides are used. Of note is that by definition, nucleotides are nucleosides which have one or more phosphate groups attached and where the claims recite nucleoside triphosphates, these are by definition, nucleotides (dNTP). It is also known

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that dNTP commonly contain adenine, thymidine, guanine and cytosine bases – see for example figure 3.6.1 of Ausubel et al. Thus, claims 13 and 15 are considered obvious as to the claim 13 and 15 nucleoside mix. As to claim 15, the components described at, e.g., column 10+ (Fung et al.) constitute a reaction mixture/buffer (undefined in current claim 15 as to specific components). Thus, it is apparent that claim 15 is obvious since one of ordinary skill in the art would, given the teachings of the Fung et al. and the Ausubel et al. references, have combined the elements described in the combined references to form a kit and use same.

Current claims 16-21 recite the dye and substituents attached to the dye. Here, Fung et al. describe A' as a linking functionality, B' as an acidic anionic group, X' as hydrogen, and Z(3-4) are hydrogen, or halo compounds or a group that maybe converted to a linking functionality column 4 line 35-59. The compound dye set forth in the Fung et al. patent meets the criteria defined by the formula shown in claim 16 with different substituents. Fung et al. also teach of a compound wherein A' is a carboxyl, B' is a is a carboxyl, X' is hydrogen and Z(3-4) are hydrogen or halo compounds it is inherent that A', X', Z(1-6) are hydrogen from the basic concept of chemistry, and can further be of a linking functionality as taught by Fung et al. Applicant claims of a kit wherein the dye consisting of a dideoxynucleoside triphosphates conjugated to a dye and a dye selected from a group consisting of 5 and 6 carboxyfluorescein. Fung et al. teach of a dye-primer conjugate in accordance with Sangers' method (column 12 line 12) and also disclose of a dye selected from 5 and 6carboxyfluorescein column 16 line

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29. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 21 recites the kit wherein the nucleic acid polymerase is Sequenase™.

Fung et al describe a nucleic acid polymerase *E. coli* DNA polymerase 1, which is necessary for the synthesis of the DNA as a function of attaching complementary nucleotide fragments to the template (Column 10 line 61+ and 11 line 1+).

USB describes of the polymerase to be T7 DNA polymerase which is highly processive and incorporates nucleotide analogs. It is obvious from the teachings of Fung et al. and USB, one of ordinary skill in the art would have substituted the USB Sequenase™ for the polymerase described and used by Fung et al.' which as combined with the Ausubel et al. and USB references would have resulted in the kit of claim 21.

No claims are allowed.

Singleton et al., eds., (1987) Dictionary of Microbiology and Molecular Biology, second edition, page 609 defines nucleoside and nucleotide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00 Monday -Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
04-12-05

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